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|--|-------------|------------------------|---------------------|------------------|
| 10/526,043 | 02/28/2005 | Hans-Peter Buchstaller | MERCK-2971 | 2965 |
| 23599 7590 03/24/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | | |
| EXAMINER | | | | |
| DAVIS, ZINNA NORTINGTON | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1625 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/24/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,043

Applicant(s)

BUCHSTALLER ET AL.

Examiner

Zinna Northington Davis

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, 13-21, 23-25 and 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-21, 23-25, 27, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11 and 28 is/are rejected.
- 7) ☒ Claim(s) 31-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

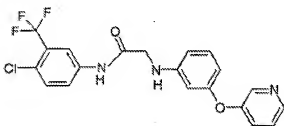
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-8, 10, 11, 13-21, 23-25, 27-38 are pending.
2. Claims 9, 12, 22, and 26 have been cancelled.
3. In the response filed December 14, 2007, Applicants have elected Group I, claims 1-8, 10, 11, 28, and 31-38, with traverse. The preferred species is depicted as



follows:

4. Applicants state is unclear whether elected Group I contains claim 11 and/or claim 28. Based upon the response filed December 14, 2007, Group I will include both of claims 11 and 28.

Response to the Remarks about The Improper Restriction Requirement

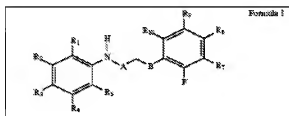
Applicants state the traversal is based upon PCT Rule 13.2. This Rule states that an independent product claim, an independent process claim specially adapted to manufacture the product, and an independent claim for use of the product is a permissible combination.

It is the Examiner's position that:

- PCT Rule 13.2 states that the unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technique features.

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- The compounds of formula I are drawn to independent and patentably distinct subject matter.
- There is no common structure which belongs to a recognized class of chemical compound.
- If it can show that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner.
- In the instant case, at least one Markush alternative is not novel. A prior art compound is disclosed in Reference 1 (cited by Applicants). At page 9, see the compound of formula I which is depicted below:



- These compounds are useful as antihyperglycemic activity which is not claimed technical feature.
- Thus, the lacks of special technical feature is apparent.
- PCT Rule 13.2 states unity of invention shall be fulfilled when there is a technical relationship among those inventions.

Applicants state Groups VI and VII are each related to Group I as intermediates and final product. The Restriction fail to provide any rationale as to why the intermediates of Groups VI and VII are not being examined with the final product of Group I.

It is the Examiner's position that:

- The intermediate compounds are drawn to independent and patentably distinct subject matter.
- There is no common structure which belongs to a recognized class of chemical compound which is similar in the compounds of Formula I, Formula III, and Formula IV.
- There would be a serious search and examination burden if restriction were not required between the intermediates and final products such as:
 - (a) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
 - (b) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
 - (c) the prior art applicable to one invention would not likely be applicable to another invention;
- There is an undue burden to search the entire scope of claims when multiple inventions are claimed.
- The requirement is still deemed proper.
- The requirement is therefore made **FINAL**.

5. Claims 13-21, 23, 24, 25, 27, 29, and 30 are withdrawn from consideration.

These claims have not been canceled.

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6. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

7. Claims 1-8, 10, 11, 28, and 31-38 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. See Reference 1 cited by Applicants. These compounds are useful as antihyperglycemic activity. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

8. Claims 1-8, 10, 11, 28, and 31-38 are objected on the grounds that the claims are drawn to an improper Markush group. In re Hamisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

9. The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties.

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The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

10. The improper Markush groups are A, L, L', M, and B'.
11. The elected compound has been examined and found to be allowable. The search has been extended beyond the elected compound.
12. The examined subject matter is as follows:

A compound of formula I wherein the N atoms of the bivalent glycine moiety is substituted by hydrogen and alkyl; L and B represent phenyl; M represents a direct bond, O, N, and S; and L' represents a six-membered heterocyclic ring. The radicals not defined herein are defined according to claim 1. Amending the claims to the examined subject matter would overcome the improper Markush rejection.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-8, 11, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "bivalent glycine amide moiety, or a derivative" is unclear. What radicals are substituted on the N-portion of the amide? What derivatives are intended? Clarification is appreciated.

B. At claims 3 and 11, it is suggested that the term "compounds" should be amended to read as "compound".

C. Claims 3-4 improperly depend upon claim 1. See the phrase "or a salt".

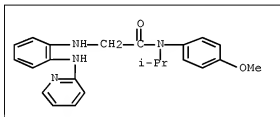
- D. Claims 6-8 are identical to claim 1.
- E. Claim 11 is confusing as written. Clarification is appreciated.
- F. At claim 28, it is suggested that the compound of formula II should be depicted.
15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-3, 6, and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Aquino et al (Reference N, cited by the Examiner).

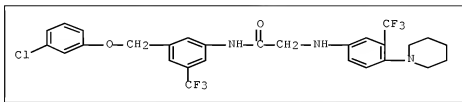
The instantly claimed compound is disclosed. At page 37, line 5, see named compound. The compound is depicted below:



- The claims are fully met when the N atoms of the bivalent glycine moiety is substituted by hydrogen and alkyl; L and B represent phenyl; M represents NH and L' represents a heterocyclic ring.
17. Claims 1, 2, 6, and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Li et al (Reference O, cited by the Examiner).
- The instantly claimed compound is disclosed. At page 82, lines 6-7, see named

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compound. The compound is depicted below:



The claims are fully met when the N atoms of the bivalent glycine moiety is substituted by hydrogen; L and B represent phenyl; M represents a direct bond; and L' represents a six-membered heterocyclic ring.

18. The Information Disclosure Statements filed February 28, 2005 has been considered.

19. Claims 31-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

21. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
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